

**OPTN/UNOS Executive Committee
Meeting Summary
August 11, 2015
Conference Call**

Betsy Walsh, JD, Chair

Discussions of the full committee on August 11, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Approval of Fall 2015 Public Comment Proposals

Before each public comment period, the Executive Committee reviews and approves which committee proposals will be distributed for community and public input. The Policy Oversight Committee (POC) performs an extensive review of the proposals and presents a recommendation to the Executive Committee prior to the vote. The POC reviews the proposals to ensure that each aligns with the OPTN strategic plan, the committee has collaborated with all the appropriate stakeholders, and the proposal is clearly written and explained. The Executive Committee is asked to review the proposals to ensure that all align with the OPTN strategic plan and the timing and level of resource allocation on each proposal is appropriate for the benchmarks outlined in the plan.

POC chair Sue Dunn presented the POC recommendations to the Committee. The POC recommended that the following proposals be distributed for public comment for the August 14-October 14 comment period:

1. Pediatric Transplantation Committee—Establish pediatric training and experience requirements
2. Data Advisory Committee—Revise data release policies
3. Kidney Transplantation Committee—Simultaneous liver kidney allocation policy
4. Kidney Transplantation Committee—Revise KPD priority points
5. Histocompatibility Committee—Updates to the HLA Equivalency Tables
6. Living Donor Committee—Requirements for therapeutic organ donation
7. Membership and Professional Standards Committee—Foreign equivalent in Bylaws
8. Membership and Professional Standards Committee—Personnel Procurement Requirement
9. OPO Committee—Reduce documentation shipped with organs
10. Policy Oversight Committee—Increase committee member terms to three years
11. Thoracic Transplantation Committee—Modify pediatric lung allocation policy
12. Pancreas Transplantation Committee--Revise facilitated pancreas allocation policy

The Committee members unanimously approved the POC's recommendation (12-yes, 0-no, 0-abstain) but requested that the Spring 2016 public comment proposals include a more elaborate analysis of the cost v. benefit for each proposal. The Committee members also agreed that future consideration of public comment proposals will need to include an analysis of how the overall portfolio is aligned with the resource allocation benchmarks outlined in the OPTN strategic plan.

With Executive Committee approval, the 12 proposals will be distributed for comment on the OPTN website (<http://optn.transplant.hrsa.gov/governance/public-comment/>) and will be presented at each of the 11 OPTN regional meetings across the country.

OPTN Response to NIH HOPE Act Research Criteria

In November 2013, the HIV Organ Policy Equity (HOPE) Act was signed into federal law. The law authorizes transplantation of HIV positive organs into HIV positive recipients. It also requires that the OPTN revise its policies no later than 2 years after the law takes effect. In June 2015, the Board approved new policies to implement these requirements. Under the next step of this process, the National Institute of Health (NIH) has developed research criteria for internal review boards (IRBs) to use in assessing whether a transplant program should be approved to participate in the HOPE Act variance. The proposed criteria was published in the Federal Register for a 60 day public comment period on June 18, 2015.

UNOS has an established 'Plan for Review of Federal Issues', as outlined in the OPTN contract. Under this process, the Executive Committee may provide an official response to federal issues on behalf of the OPTN. The OPTN's HOPE Act working group, which is comprised of several OPTN/UNOS committees drafted a proposed response for the Committee's review and consideration. Rich Pietroski, Chair of the HOPE Act working group and Executive Committee member, presented the draft response to the Committee.

The Committee discussed whether the proposed draft should be strengthened to highlight greater concerns about the inclusion of living donors into the research study. Mr. Pietroski reported that the working group had discussed this issue and there is no consensus within the transplant community about whether it is appropriate to include living donors. The federal statute, regulations, and research criteria are all silent on the issue. Ultimately, the working group recommends that the decision be made by each transplant center's IRB and that the OPTN not take an official stance on the issue.

The Committee also discussed whether the response should express concerns about the OPTN bearing responsibility for additional data collection as part of the research efforts. The Committee ultimately felt that this was not necessary because there was no explicit reference to the OPTN bearing this responsibility in the statute or NIH research criteria.

Ultimately, the Committee unanimously approved the response recommended by the HOPE Act working group (12-yes, 0-no, 0-abstain).

Retrospective Review of Clerical Changes to OPTN Policy

In November 2014, the Board of Directors approved a change to the OPTN Bylaws that permits UNOS staff to make clerical, non-substantive changes to the bylaws and policies. The Bylaws specifies that the Executive Committee must retrospectively review any corrections made. The Committee reviewed and approved unanimously changes made to policy in the last six months.

Clerical changes criteria: The new rule allows UNOS staff to make the following types of clerical changes:

- Capitalization or punctuation, as needed to maintain consistency with current policy
- Typographical, spelling, or grammatical errors
- Lettering and numbering of a rule or the subparts of a rule, according to style conventions in current policy
- Cross-references to rules or sections that are cited incorrectly because of subsequent repeal, amendment, or reorganization of the sections cited.

The UNOS policy department staff presented a number of clerical changes that had been made since the new policy became effective on February 1, 2015.

Clerical Change	Reason
Bylaws D.5 Transplant Program Key Personnel	Deleted obsolete reference to <i>Appendix J: Membership and Personnel Requirements for Joint Heart and Lung Programs</i> , which no longer exists as of June 2014.
Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination	Corrected typo that said “The following provisions of Appendix D do not apply to VCA transplant programs,” with the correct reference to Appendix K.
Policy 14.4.B: Living Donor Medical Evaluation Requirements, Table 14-6: Requirements for Living Donor Medical Evaluations	Removed unnecessary period.
Policy 14.4.B: Living Donor Medical Evaluation Requirements, Table 14-6: Requirements for Living Donor Medical Evaluations	Corrected typo from <i>preventative</i> to <i>preventive</i> in “U.S. Preventive Services Task Force”
Policy 14.4.C, Table 14-7: Additional Requirements for Medical Evaluation of Living Kidney Donors	Deleted repeated language that introduces list of items required for the kidney-specific person history. Removed the first colon to combine the two lead clauses to only one, using a comma between. This also required making the letter “A” before <i>kidney-specific</i> a small “a.”

The Committee approved these changes unanimously (12-yes, 0-no, 0-abstain).

Upcoming Meeting(s)

- September 21, 2015
- October 19, 2015
- November 16, 2015
- December 1, 2015